

12/20/93

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of)
)
 J.A.G. Industries, Inc.,) IF&R Docket No. III-429-C
)
 Respondent)

Federal Insecticide, Fungicide and Rodenticide Act -- Unlawful Formulation, Mislabeling -- Respondent's pesticide shipments were unlawfully formulated, because the source of the active ingredient was different from the one listed in the pesticide's registration, even though EPA agreed that both sources were "identical;" and the shipments were mislabeled, because their labels lacked information required by the Act and the absence was excused neither by a possibly confusing EPA memorandum received by Respondent nor by the bulk nature of the shipments.

RULING ON MOTIONS FOR
PARTIAL ACCELERATED DECISION AND DISMISSAL

This Ruling addresses a Motion for Partial Accelerated Decision filed by Complainant--the Air, Toxics & Radiation Division, Region III, U.S. Environmental Protection Agency ("EPA")--and a Motion for Dismissal filed by Respondent--J.A.G. Industries, Inc. Complainant initiated this proceeding under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. §§ 136-136y ("FIFRA"), and regulations issued pursuant to FIFRA and codified in 40 C.F.R. Subchapter E ("the Regulations").

The November 16, 1990 Complaint alleged that in 1990 Respondent twice sold and distributed a pesticide that was unlawfully formulated and mislabeled. After extended efforts to negotiate a settlement proved unsuccessful, the parties submitted Stipulated Facts, and agreed to resolve the question of Respondent's alleged liability through written submissions.

Complainant moved for a partial accelerated decision declaring Respondent to have violated FIFRA as charged, and Respondent moved for a dismissal on the ground that no violation had been shown. Each party replied to the Motion of the other and, with Respondent's June 21, 1993 reply, the record is ready for this Ruling.

Unlawful Formulation

Facts

Parties' Positions. The facts giving rise to this charge are as follows. On January 15, 1990 Respondent contracted to produce and deliver to Aquarium Pharmaceuticals, Inc. about two million tablets of the pesticide "Algae Destroyer." The active ingredient in Algae Destroyer is Simazine 80%, which may alternatively be obtained from either of two Aquazine products or from a product named Princep 80W.

What underlies Complainant's charge of unlawful formulation is Respondent's use of Princep 80W as the Simazine 80% source in its production of Algae Destroyer. The problem is that this production occurred at a time when only the two Aquazine products had been registered with EPA as components of Algae Destroyer; Princep 80W was not so registered until two months later. Respondent's defense is a stipulation of the parties that Princep 80W "is identical to" one of these Aquazine products.¹

Registration of Algae Destroyer. Aquarium Pharmaceuticals, Inc., as part of its initial registration of Algae Destroyer with EPA in 1986, submitted an EPA form titled "Confidential Statement of Formula." The largest portion of this form requires a statement of the "Components in Formulation." For each component, an entry is required of its name and CAS number, supplier, purpose in formulation, weight and percentage characteristics of its use in the formulation, and its EPA Registration Number.²

Aquarium Pharmaceuticals, Inc., in a form dated November 13, 1986, listed four components for Algae Destroyer. The first was "Aquazine ... Simazine 80%," with "CIBA-Geigy Corp" as the supplier, and an EPA Registration Number of 100-570.³

On October 15, 1989, Aquarium Pharmaceuticals, Inc. requested EPA to approve an alternate formulation for Algae Destroyer, again submitting a Confidential Statement of Formula form. On this form, it again listed four items as Components in Formulation. The first item listed in this request, in substitution for the component named above, was another product based on Simazine, "Aquazine 90

¹ Stipulated Facts 4 ¶17 (March 23, 1993).

² Respondent's Prehearing Exchange, Exhibit 9 (April 30, 1991); Stipulated Facts 1 ¶4 (March 23, 1993).

³ Respondent's Prehearing Exchange, Exhibit 9 (April 30, 1991); Stipulated Facts 1 ¶4 (March 23, 1993). In the listing of the supplier as "CIBA-Geigy," the capitalization of the second through fourth letters in "CIBA" was, as far as the record of this case reflects, simply a typographical error.

DWG," with "Ciba-Geigy Corp" again as the supplier, and with an EPA Registration Number of 100-650. EPA approved this alternate formulation on November 16, 1989.⁴

Respondent's Production. Prior to Respondent's production of Algae Destroyer, it received from Aquarium Pharmaceuticals, Inc. a "Work Sheet" specifying, as one of the four product ingredients, "3.5% Simazine (80%) * Ciba Geigy ... EPA Reg. No. *100-570."⁵ To obtain the ingredients, Respondent sent to Coburn Chemical, Inc., a Ciba-Geigy distributor, a January 16, 1990 purchase order that requested simply "Simazine," without further specification, such as the EPA Registration Number.⁶

To record its subsequent delivery to Respondent, Coburn Chemical, Inc. sent a bill of lading⁷ and an invoice⁸ that recorded the delivery simply of "Simazine." The labeling of the Simazine as received by Respondent identified its source as Princep 80W (EPA Registration Number 100-437) from Ciba-Geigy.⁹

During February 1-19, 1990 Respondent produced about two million tablets of Algae Destroyer,¹⁰ using Princep 80W (EPA

⁴ Respondent's Prehearing Exchange, Exhibit 10 (April 30, 1991); Stipulated Facts 1, ¶5 (March 23, 1993). The name of the Aquazine product in the text--"Aquazine 90 DWG"--is taken from Respondent's Prehearing Exchange; in the Stipulated Facts it is called "Aquazine 90W DG."

⁵ Emphasis in original. Respondent's Prehearing Exchange, Exhibit 15 (April 30, 1991); Stipulated Facts 2 ¶7 (March 23, 1993).

⁶ Respondent's Prehearing Exchange, Exhibit 16 (April 30, 1991).

⁷ Id. Exhibit 17.

⁸ Id. Exhibit 18.

⁹ Id. Exhibit 20. The listing for Exhibit 20 in Respondent's Prehearing Exchange stated that this labeling was received January 19, 1990, whereas Respondent's Answer, at 2 ¶6 (December 10, 1990), suggested that the date was February 19, 1990. Apparently the January date is correct, because the parties' Stipulated Facts, at 2 ¶9 (March 23, 1993), stated that "[b]etween February 1 and February 19, 1990 Respondent produced approximately 2 million tablets of Algae Destroyer"

¹⁰ Stipulated Facts 2 ¶9 (March 23, 1993).

Registration Number 100-437) as the source of the active ingredient Simazine.¹¹ On February 7, 1990, Respondent shipped to Aquarium Pharmaceuticals, Inc. about half a million of the tablets,¹² and on February 21, 1990 another 1.5 million.¹³

Princep 80W. Further as to Princep 80W (EPA Registration Number 100-437), in April 1990, Aquarium Pharmaceuticals, Inc. requested, and EPA granted, approval for its use as an alternate source of Simazine for Algae Destroyer.¹⁴ In their submissions for this case, Complainant and Respondent stipulated that "Princep 80W (EPA Registration No. 100-437) is identical to ... Aquazine (EPA Registration No. 100-570)."¹⁵

Discussion

Statute. Complainant charged that Respondent's two shipments of Algae Destroyer to Aquarium Pharmaceuticals, Inc. violated Section 12(a)(1)(C) of FIFRA (7 U.S.C. §136j(a)(1)(C)). That Section declares as follows.

[I]t shall be unlawful ... to distribute or sell ... any registered pesticide the composition of which differs ... from its composition as described in the statement ... in ... its registration"

The dispute between the parties centered on the meaning in the quoted statutory phrase of "composition."¹⁶ Complainant argued that the Algae Destroyer shipped by Respondent to Aquarium Pharmaceuticals, Inc. in February 1990 was unlawfully formulated because its composition differed from the composition in the

¹¹ Id. ¶10.

¹² Id. ¶11.

¹³ Id. ¶12.

¹⁴ Id. 3, ¶13.

¹⁵ Id. ¶17.

¹⁶ As to the statutory phrase "to distribute or sell," Complainant noted that Section 2(gg) of FIFRA (7 U.S.C. § 136(gg)) defines it to include "hold for distribution, ... hold for shipment, ship, deliver for shipment, release for shipment" Memorandum in Support of Complainant EPA's Motion for Partial Accelerated Decision 14 (April 30, 1993). Complainant concluded that Respondent shipped the Algae Destroyer to Aquarium Pharmaceuticals, Inc. within the meaning of this quoted phrase, and Respondent did not dispute the point.

registration statement for this pesticide.

Complainant's point was that the shipped Algae Destroyer had been made from Princep 80W, not from either of the Aquazine products that Aquarium Pharmaceuticals, Inc. had listed in its registration statements with the Agency up to that time. As noted above, Aquarium Pharmaceuticals, Inc. did not include Princep 80W in a registration statement until April 1990.

Respondent denied this charge of unlawful formulation. The composition at issue was in fact the same, countered Respondent, because Princep 80W (EPA Registration Number 100-437) "is identical," per the parties' stipulation, to the Aquazine product (EPA Registration Number 100-570) listed by Aquarium Pharmaceuticals, Inc. in its October 1989 registration statement.

Regulations, Forms. "Composition" as used in Section 136j(a)(1)(C) is not defined in FIFRA or in the Regulations. Nor has any relevant case been found. Section 158.155 of the Regulations (40 C.F.R. §158.155), which states some of the information that must be included in an application to register a pesticide, may supply some meaning for "composition." This section provides, in pertinent part, as follows.

§ 158.155 Product composition.

Information on the composition of the pesticide product must be furnished....

(a) Active ingredient. The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product....¹⁷

Did the composition of Respondent's Algae Destroyer violate this regulatory section? The answer is not entirely clear from the language of the section itself. But the answer becomes clearer from an examination of the Confidential Statement of Formula forms submitted by Aquarium Pharmaceuticals, Inc. as part of its registration of Algae Destroyer.

The two forms that were part of the registration at the time of Respondent's shipments of Algae Destroyer to Aquarium Pharmaceuticals, Inc. were described briefly above.¹⁸ The component containing Simazine was listed in one as "Aquazine ... Simazine 80%," with an EPA Registration Number of 100-570, and in

¹⁷ Emphasis in original omitted.

¹⁸ See text supra accompanied by notes 2 and 3.

the other as "Aguazine 90 DWG," with an EPA Registration Number of 100-650. The Simazine used in Respondent's production of the Algae Destroyer that was distributed and sold to Aquarium Pharmaceuticals, Inc., however, came from Princep 80W, with an EPA Registration Number of 100-437.

Composition Was Different. Does that difference in names and in EPA Registration Numbers constitute a difference in "composition" within the meaning of FIFRA Section 136j(a)(1)(C), even though "Princep 80W (EPA Registration No. 100-437) is identical to ... Aquazine (EPA Registration No. 10-570)"? The answer to that question is in the affirmative.

This answer follows from the plain language of Section 136j(a)(1)(C). The test is whether "the composition" of the Algae Destroyer shipped by Respondent "differ[ed] ... from its composition as described in the [registration] statement." Primary elements of that description, as required by the EPA form, were each component's name and EPA Registration Number. In both of these respects, the composition of the Algae Destroyer shipped to Aquarium Pharmaceuticals, Inc. "differ[ed] ... from its composition as described in the [registration] statement."

That "Princep 80W (EPA Registration No. 100-437) is identical to ... Aquazine (EPA Registration No. 100-570" fails to overcome their differences in name and EPA Registration Number. This identity may legitimately mitigate any civil penalty to be assessed; certainly it vastly reduced the risk of any harm coming from this difference in components. But this identity does not undo the differences between the "composition" of the Algae Destroyer "distributed or [sold]" to Aquarium Pharmaceuticals, Inc. and the "composition" of this pesticide "as described in the [registration] statement." Both the name and the EPA Registration Number of the Simazine source that went into each were clearly different.

Statutory Purpose. To hold that these differences in name and EPA Registration Numbers constitute a difference in "composition" within the meaning of FIFRA Section 136j(a)(1)(C) is not to enforce a mere formality. This name and number in the registration statement is important: EPA uses them to determine whether the pesticide is sufficiently safe to be approved for distribution and sale. EPA knows the properties of chemicals that are registered with it. Thus, when registration is requested for a pesticide to be made from these chemicals, EPA has the information necessary to evaluate the safety of the resulting product.

To sell or distribute a pesticide made from a substituted component with a different name and EPA Registration Number defeats the purpose of this EPA evaluation. That the substituted component may later prove to be identical to a component in the pesticide's registration statement obviously reduces the risk of harmful

effects from the sale or distribution. But the acceptability of any substitution is a question entrusted by the statute to EPA decision, not left to resolution by the producer or by fortuitous chance. Thus the integrity of FIFRA's system for registering pesticides requires that the differences in name and EPA Registration Number in this case be ruled a violation of Section 135j((a)(1)(C).

Strict Liability. FIFRA is a strict liability statute. Consequently, Complainant has sufficiently proved its case by establishing that Respondent "distribute[d] or [sold]" an Algae Destroyer that had a "composition ... differ[ing] from its composition as described in the [registration] statement."

But the record shows also that Respondent was negligent in allowing this difference in composition to occur. The "Work Sheet" that Respondent received from Aquarium Pharmaceuticals, Inc. specified the source of the Simazine as a Ciba-Geigy product with the EPA Registration Number 100-570.¹⁹

Respondent, however, sent its Ciba-Geigy distributor a purchase order that requested "Simazine" without any designation of EPA Registration Number.²⁰ The labeling of the Simazine that Respondent then received from the distributor identified its source as having the EPA Registration Number 100-437,²¹ which should have alerted Respondent to a difference from the ingredient listed on its "Work Sheet."

Further Questions. In arguing Complainant's charge of an unlawful formulation, the parties debated two further questions. The first was whether notifying EPA of an intended substitution of Princep 80W for one of the approved Aquazine products was the duty of Respondent or of Aquarium Pharmaceuticals, Inc. The second was whether it makes any difference that this production of Algae Destroyer was Respondent's first production of a pesticide.

Neither of these questions, however, is relevant to determining whether Respondent distributed or sold an unlawfully formulated pesticide, as charged. The first question lacks significance because the charge asserted by the Complaint is the alleged unlawful formulation, not any failure of required notification. The second question is without significance because FIFRA Section 136j(a)(1)(C) applies alike to new and to experienced parties, without distinction.

¹⁹ See text supra accompanied by note 5.

²⁰ See text supra accompanied by note 6.

²¹ See text supra accompanied by note 9.

Decision. The decision is that Respondent's two shipments to Aquarium Pharmaceuticals, Inc. of Algae Destroyer were unlawfully formulated in violation of Section 12(a)(1)(C) of FIFRA (7 U.S.C. § 136j(a)(1)(C)). Accordingly, Complainant's Motion for Partial Accelerated Decision on this issue is granted. For the same reason, Respondent's Motion for Dismissal of this charge is denied.

There remains the question of the appropriate sanction. The parties will be directed to try to negotiate a resolution of this question. In their negotiations, the identity of Princep 80W and of one of the approved Aquazine products is clearly a factor that should mitigate the sanction.

Mislabeling

Facts

Background. The facts giving rise to this charge included stipulations by the parties as to what the labels on the Algae Destroyer shipped by Respondent to Aquarium Pharmaceuticals, Inc. did and did not contain. They stipulated that the labels "contained the following information."

MANUFACTURED FOR:
 AQUARIUM PHARMACEUTICALS
 50 EAST HAMILTON STREET
 CHALFONT, PA 18914
 ALGAE DESTROYER TABLETS
 API CODE# 2525 P.O.# 748
 LOT # API-011 QTY. 10,000²²

The parties then stipulated that "the labels ... did not contain the following information required by 40 C.F.R. § 156.10."

- the establishment registration number of Respondent
- directions for use of the product
- warning or caution statements
- warning or precautionary statements concerning hazards to children, the environment, and physical and chemical hazards
- an ingredient statement
- the use classification under which it is registered
- the net weight or measure of the contents

²² Stipulated Facts 3, ¶14 (March 23, 1993).

- the EPA registration number assigned to Algae Destroyer²³

Before beginning its production of Algae Destroyer, Respondent submitted to EPA an Application for Registration of Pesticide-Producing Establishment,²⁴ and received in return a Notification of Registration of Pesticide-Producing Establishment, dated January 18, 1990.²⁵ Accompanying the Notification was a two-page EPA memorandum. Pertinent parts of this memorandum are quoted below.

SUBJECT: Notification of Pesticide-Producing
Establishment Registration

TO: Pesticide Producers

The enclosed document serves as notification of registration of the establishment(s) for which establishment registration application was made....

ESTABLISHMENT NUMBER:

....

IMPORTANT:

It should be noted that the establishment number is not a substitute for the EPA product registration number (EPA Reg. No.). Both numbers must appear on all EPA registered products....

LABELING:

Section 167.4 of the regulations promulgated pursuant to Section 7 (38 F.R. 30558) requires that the establishment number preceded by the words "EPA Est.", must appear on the label or immediate container of each pesticide product released for shipment from the registered producing establishment. This number must also appear on the outside container or wrapper of the package if there be one through which the establishment number on the immediate container cannot be clearly read.

....

PESTICIDES REPORTS:

²³ Emphasis in original. Id. ¶15.

²⁴ Respondent's Prehearing Exchange, Exhibit 1 (April 30, 1991).

²⁵ Id. Exhibit 2; Stipulated Facts 2, ¶8.

....

ACCEPTABLE LABELING TECHNIQUES FOR COMPANIES
WITH MORE THAN ONE REGISTERED ESTABLISHMENT

....

However, in no circumstances may the EPA Establishment Number be combined with the EPA Product Registration Number.²⁶

Finally, the parties stipulated two further points about Respondent's shipments of Algae Destroyer to Aquarium Pharmaceuticals, Inc. First, the shipments were bulk packaged; and, second, they were shipped to Aquarium Pharmaceuticals, Inc. for final repackaging.²⁷

Parties' Positions. Complainant charged that the absence from Respondent's shipments of the labeling information as stipulated above by the parties constituted a violation of FIFRA. Complainant cited Section 12(a)(1)(E) of FIFRA (7 U.S.C. § 136j(a)(1)(E)), which declares "it ... unlawful ... to distribute or sell ... any pesticide which is ... misbranded." Both parties treated "misbranded" as the same as "mislabeled" for the purposes of this case.

For a definition of misbranding, Complainant cited Section 2(q) of FIFRA (7 U.S.C. § 136(q)) and, from the Regulations, Part 156 (40 C.F.R. Part 156). Complainant contended that Part 156 applied to Respondent's shipments, and therefore the absence of the labeling information required by Section 156.10 contravened FIFRA.

Respondent's answer was essentially twofold. First, Respondent maintained that the EPA memorandum it received in conjunction with the Notification of Registration of Pesticide-Producing Establishment was misleading, and that accordingly Complainant should be barred from prosecuting its mislabeling charge. Second, Respondent argued that Section 156.10 applies only to retail packaging, and not to Respondent's bulk shipments.

Respondent: Misleading EPA Memorandum. To support its first defense, Respondent noted that the memorandum's paragraph on "Labeling" cited a regulatory section and a Federal Register publication by EPA. But, Respondent noted, the regulatory section--"Section 167.4 of the regulations"--no longer existed in January

²⁶ Emphasis in original. Respondent's Prehearing Exchange, Exhibit 3 (April 30, 1991); see also Stipulated Facts 2, ¶8 (March 23, 1993).

²⁷ Stipulated Facts 2, ¶¶11, 12 (March 23, 1993).

1990 when Respondent received this memorandum.

As to EPA's Federal Register publication, Respondent observed that it defined "produce" as follows: "to manufacture, prepare, propagate, compound, or process any pesticide ... or to repackage or otherwise change the container of any pesticide or device."²⁸ Further, Respondent observed, the Federal Register publication contained a Section 167.4, titled "Labeling requirements," which included a subsection (a) titled "Establishment number." That subsection, as quoted by Respondent, stated: "The only Establishment Registration Number which shall appear on the label is that of the final establishment at which the product was produced."²⁹

Respondent's argument is apparently that the above quoted provisions entitled it to conclude as follows. Since Aquarium Pharmaceuticals, Inc. was sent the Algae Destroyer for final packaging,³⁰ it thereby became a producer of the pesticide, pursuant to the above definition of "produce." Section 167.4(a) therefore mandated only that the label after the final repackaging should show just the Establishment Registration Number of Aquarium Pharmaceuticals, Inc. as "the final establishment at which the product was produced." Thus, evidently in Respondent's view, it had been led by EPA's memorandum reasonably to believe that no labeling requirements existed with which it had to comply in shipping the Algae Destroyer to Aquarium Pharmaceuticals, Inc. for final packaging.³¹

Complainant's Rejoinder. Complainant rejoined that Respondent was unreasonable in relying on the memorandum accompanying the Notification of Pesticide-Producing Establishment Registration for anything other than what it was, viz., a part of the notification of registration. The only labeling information that it purported to convey, according to Complainant, related solely to the listing of the establishment registration number. As stated by Complainant, "No reasonable person could conclude that

²⁸ Respondent's Memorandum in Support of Respondent's Motion for Dismissal 21 ((May 20, 1993).

²⁹ Id. 22.

³⁰ See text supra accompanied by notes 12-13.

³¹ Respondent, in addition to speaking generally of its reliance on EPA's memorandum, also mentioned entrapment twice, but did not develop that argument. Respondent's Memorandum in Support of Respondent's Motion for Dismissal 24, 27 ((May 20, 1993). The record of the case contains no significant evidence to support a defense of entrapment.

this document is EPA's exclusive and definitive statement concerning the labeling of pesticides."³²

Retail vs. Bulk Sales. Respondent's second argument was that Section 156.10 of the Regulations applies only to retail packaging, and Respondent's shipments were packaged in bulk. To support this argument, Respondent made three points.

First, Respondent noted that the present Section 156.10 was once numbered Section 162.10 and was contained within Section 162, which was titled "Registration, Reregistration and Classification Procedures."³³ Respondent contended that Section 162, chiefly by virtue of this nomenclature in its title, was aimed mainly at registrants, apparently meaning in the instant case Aquarium Pharmaceuticals, Inc., and aimed more specifically at "registrant consumer labeling."³⁴ Since the labeling requirements of the old Section 162 have been transferred intact to the present Section 156.10, Respondent claimed that it too targets primarily "registrant consumer labeling."³⁵

Complainant's rejoinder was that nothing in FIFRA restricted its labeling requirements to retail as opposed to bulk sales. Therefore Complainant concluded that the bulk sale character of Respondent's sales in no way excused it from compliance with Section 156.10.

Second, Respondent noted that former Section 162.10(a)(2), now Section 156.10(a)(2), regarding prominence and legibility, requires labeling information to be in a form "render[ing] it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." Similarly, Respondent observed that former Section 162.10(a)(4), currently Section 156.10(a)(4), concerning "Placement of Label," contains a reference to "a part of the package as customarily distributed or sold." From these quoted phrases, Respondent drew the conclusion that all of Section 156.10 is aimed at "registrant consumer labeling."³⁶

Complainant did not reply specifically to this argument by Respondent. But presumably Complainant's reply would be subsumed

³² EPA's Reply to Respondent JAG's Response to EPA's Motion for Accelerated Decision 6 (June 9, 1993).

³³ Respondent's Memorandum in Support of Respondent's Motion for Dismissal 25 (May 20, 1993).

³⁴ Id.

³⁵ Id.

³⁶ Id.

within its basic position that nothing in FIFRA's language provides any basis for excepting all bulk sales from its labeling requirements.

Third, Respondent cited one subsection of Section 156.10 that does make separate provision for certain bulk shipments. Section 156.10(a)(4) concerns "Placement of Label," and subsection (ii) defers to Department of Transportation rules for "Tank cars and other bulk containers" (emphasis in original).

Complainant's rejoinder was that this special provision applies only "to bulk containers such as tanker cars capable of carrying and discharging huge quantities of a pesticide ... [and] does not apply where, as here, the pesticide is placed in numerous cardboard boxes, loaded into a tractor trailer operated by a common carrier, and (most likely) intermixed with other goods."³⁷ Complainant added that application of Section 156.10's labeling requirements is genuinely needed in situations such as the instant case to protect the public. As explained by Complainant, these requirements are intended to protect not only ultimate retail users of the pesticide, but also the employees of common carriers and even emergency workers who could come into contact with a pesticide in the event of an accident during transportation.

Discussion

Part 156 of the regulations (40 C.F.R. Part 156) issued by EPA pursuant to FIFRA is titled "Labeling Requirements for Pesticides and Devices," and it contains the following subsection.

§ 156.10 Labeling Requirements.

(a) General--(1) Contents of the label. Every pesticide products [sic] shall bear a label containing the information specified by the Act and the regulations in this part.

(emphasis in original)

The parties have stipulated that the labels on the Algae Destroyer shipped by Respondent to Aquarium Pharmaceuticals, Inc. lacked certain information required by this Section 156.10. Neither of the defenses advanced by Respondent--that it was reasonably misled by an EPA memorandum, or that this Section applies only to retail sales--succeeds in avoiding the conclusion that Respondent's shipments violated this Section. Consequently, Respondent's shipments were mislabeled under the Regulations; and this mislabeling means that they were misbranded under Section

³⁷ EPA's Reply to Respondent JAG's Response to EPA's Motion for Accelerated Decision 8 (June 9, 1993).

12(a)(1)(E) of FIFRA (7 U.S.C. § 136j(a)(1)(E), as charged by the Complaint.

EPA Memorandum. Respondent's argument on this point fails on two grounds. In the first place, the labeling on Respondent's shipments clearly transgressed Section 156.10 of the Regulations. In this situation, the governing legal principle is clear. A series of judicial cases has held a party to compliance with a lawfully promulgated regulation, and has barred a party from excusing any noncompliance by citing a conflicting agency statement.³⁸ Thus Respondent's asserted reliance here on the EPA memorandum is unavailing.

In the second place, even if a reasonable reliance on the EPA memorandum could supply an excuse, Respondent's reliance was not sufficiently reasonable. Respondent's entire argument is based on the paragraph in the memorandum titled "Labeling." That paragraph by its whole terminology focused only on what the label must contain regarding the establishment registration number, not on what the label must contain regarding any pesticide.

That conclusion is reinforced by the paragraph immediately preceding the "Labeling" paragraph and by the last sentence of the memorandum. Both refer to a requirement that the label for an EPA registered product include the product's EPA registration number. Yet nothing about such a product's EPA registration number appears in the paragraph titled "Labeling." The logical inference from that absence is that the "Labeling" paragraph spoke only to the labeling requirements for the establishment registration number, and not to labeling requirements generally.

Essentially the same may be said of Respondent's reference to EPA's Federal Register publication. Section 167.4(a) therein, quoted by Respondent, by its language clearly referred only to the labeling requirements for the establishment registration number. Nothing in it suggested that it addressed the universe of labeling requirements.

Nonetheless, to hold that Respondent's asserted reliance on the memorandum's "Labeling" paragraph for all Respondent's labeling requirements was unreasonable is not to say that Respondent's reading totally lacked plausibility. Nor is it to say that the EPA memorandum could not have been clearer and more helpful.

³⁸ See U.S. E.P.A. v. Environmental Waste Control, Inc., 917 F.2d 327 (7th Cir. 1990). See also Emery Min. Corp. v. Secretary of Labor, 744 F.2d 1411 (10th Cir. 1984). See generally Cheers v. Secretary of Health, Ed., & Welfare, 610 F.2d 463 (7th Cir. 1979); Flamm v. Ribicoff, 203 F.Supp. 507 (S.D. N.Y. 1961).

Certainly the memorandum's "Labeling" paragraph was amiss in referring the reader to a regulatory section that no longer existed, viz., "Section 167.4 of the regulations." And certainly the paragraph would have been more helpful had it stated explicitly that it spoke to the labeling requirements only for the establishment registration number, and that the reader should consult other materials for additional labeling requirements. In sum, the somewhat confusing nature of the memorandum paragraph is a factor that can legitimately moderate the sanction to be imposed on Respondent for this violation.

Retail vs. Bulk. This defense by Respondent is unsupported by either FIFRA or the Regulations. Respondent's citation of the former Section 162 and Section 162.10 is unpersuasive. The title of the former Section 162, cited by Respondent, lacks much significance, because the title of the present Part 156 is "Labeling Requirements for Pesticides and Devices." Moreover, nothing in the labeling sections of FIFRA, as pointed out by Complainant, nor in Part 156 of the Regulations limit their labeling requirements to retail packaging.

This same basic point governs Respondent's citation of two isolated phrases in Section 156.10, a Section sufficiently extensive that it occupies eight double-columned pages of the Code of Federal Regulations. These two phrases are much too limited in meaning to serve as a basis for restricting the application of the whole Section, especially in the absence of any such restriction expressed anywhere in the Section itself.

Lastly, Respondent cited a reference in Section 156.10 to a special provision for bulk containers. But Complainant showed that this special provision does not apply to Respondent's situation. Moreover, that Section 156.10 makes a special provision for this one type of bulk transaction suggests that, absent such an express special provision, all transactions, retail and bulk alike, are subject to the Section's basic requirements.

Further Question. In arguing the mislabeling charge, the point was again raised by Respondent that its production of Algae Destroyer was its first production of a pesticide. As was concluded above in the Discussion in connection with the unlawful formulation charge, this point is irrelevant to a determination of whether Respondent mislabeled its shipments of Algae Destroyer.

Decision. The decision is that Respondent's two shipments violated Section 12(a)(1)(E) of FIFRA (7 U.S.C. § 136j(a)(1)(E)). Accordingly, Complainant's Motion for Partial Accelerated Decision on this issue is granted. For the same reason, Respondent's Motion for Dismissal of this charge is denied.

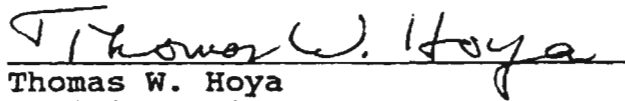
As to the proper sanction, the parties will be directed to try to negotiate it. In their negotiations, they may consider the

deficiencies of the EPA memorandum sent Respondent in conjunction with the Notification of Pesticide-Producing Establishment Registration.

Ruling

Respondent's shipments of Algae Destroyer to Aquarium Pharmaceuticals, Inc. on February 7 and February 21, 1990 were unlawfully formulated, in violation of Section 12(a)(1)(C) of FIFRA (7 U.S.C. § 136j(a)(1)(c)), and were mislabeled, in violation of Section 12(a)(1)(E) of FIFRA (7 U.S.C. § 136j(a)(1)(E)). Accordingly, Complainant's Motion for Partial Accelerated Decision is granted, and Respondent's Motion for Dismissal is denied.

The parties are directed to try to negotiate an appropriate sanction to settle this case. Complainant is directed to report by January 31, 1994 on the status of the parties' negotiations.


Thomas W. Hoya
Administrative Law Judge

Dated: December 20, 1993

IN THE MATTER OF J.A.G. INDUSTRIES, INC., Respondent
Docket No. IF&R-III-429-C

Certificate of Service

I certify that the foregoing Ruling On Motions For Partial Accelerated Decision and Dismissal, dated December 20, 1993, was sent this day in the following manner to the addressees listed below.

Original by Regular Mail to:

Lydia A. Guy
Regional Hearing Clerk
U.S. Environmental Protection
Agency
841 Chestnut Building
Philadelphia, PA 19107

Copy by Regular Mail to:

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